DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

November 15, 2001

Ref: 2002-DAL-WL-05

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Shane Islam
Senior Partner
Seafood Wholesalers Limited
P.O. Box 571196
Houston, Texas 77257

Dear Mr. Islam:

We inspected your seafood operation at 1201 Weiss Street, Houston, Texas, on September 25 - October 2, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. These deviations cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

Our inspection revealed your processing of seafood products deviates from the regulations contained in 21 CFR Part 123 as follows:

- You must have written HACCP plans that list the critical limits that must be met at each critical point, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxin-forming species does not insure that fish are being maintained at appropriate temperatures throughout transport.

- You must have written HACCP plans that list the critical control points that must be met, to comply with 21 CFR 123.6(c)(2). Specifically, the storage critical control point addressing the receipt and storage of scombrotoxin-forming species fish requires the continuous monitoring of the temperature and the cooler temperatures were not being adequately monitored. The monitoring frequency procedure also references the checking of ice coverage twice a day and the coverage of ice for products in Cooler #1 was not being documented. If your firm chooses to change a HACCP plan monitoring

procedure, your HACCP plan should adequately reflect the procedure your firm is currently using.

- You must have written HACCP plans that list the critical limits that must be met, to comply with 21 CFR 123.6(c)(2) and (3). However, your firm's HACCP plan for fresh picked crabmeat was inadequate in that the critical limit component for receiving did not insure that fresh picked crabmeat products were being maintained at an appropriate temperature throughout transport. The plan did not have a critical control point that addressed the storage of fresh picked crabmeat.

- You must take appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take corrective action when the temperature in Cooler #1 rose above 40 degrees F on September 10-15, 2001.

- You must retain all required records at your processing facility for refrigerated seafood products for at least one year after the date they were prepared, to comply with 21 CFR 123.9(b)(1). However, your firm could not locate the aquaculture species third party certificates required by your HACCP plan.

- You must monitor sanitation and maintain complete sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(b) and (c). However, your firm did not have adequate sanitation monitoring records or procedures in all eight areas of sanitation, including hand-washing/sanitizing.

You advised the investigator during this inspection and the previous inspection that your firm would be moving to a new facility. You advised that the doors and floors would not continue to be a sanitation concern. If you continue to delay your move, please outline what corrections you have made to your current location to assure no openings exist under doors and the floors are adequately repaired. This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection your firm was issued a Form FDA-483 which is a list of the Investigators' observations of deviations noted during the inspection. A copy of the FDA-483 is enclosed. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections. Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

MAC:gsg

Enclosure